

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Randall B. Lauffer et al.      Art Unit : 1619  
Serial No. : 09/887,706      Examiner : Michael G. Hartley  
Filed : September 8, 2000  
Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

**Mail Stop Issue Fee**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(B)**

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. Attached herewith is a copy of the Notice of Allowance including a Determination of Patent Term Adjustment under 35 U.S.C. 154(b), mailed July 9, 2004, for the above-referenced application. The Notice of Allowance states that the Patent Term Adjustment at allowance is 312 days. Reconsideration of the Patent Term Adjustment calculation to decrease Applicant Delay from 127 days to 37 days, and to increase Total PTA from 312 to 402 days, is respectfully requested.

10/08/2004 FMETEK12 00000096 09887706

03 FC:1455

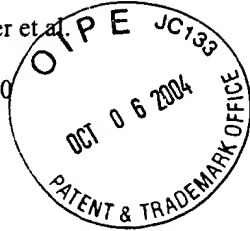
200.00 DP

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV467324605US

October 6, 2004

Date of Deposit



**I. REVIEW OF PATENT TERM ADJUSTMENT CALCULATION**

A review of the Patent Term Adjustment History in the PAIR system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

1. The PTO mailed a Notice of Incomplete Nonprovisional Application on March 29, 2002. The three-month period for response expired on June 29, 2002. The PAIR system indicates the "Application is Now Complete" on August 29, 2002, thereby according an Applicant Delay of 61 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 0 days, as outlined further below.
2. The PTO mailed a delayed first non-final Office Action on January 21, 2003, thereby according a PTO Delay of 439 days. Applicants' concur with this patent term adjustment calculation.
3. Applicants submitted a response on May 21, 2003, to the non-final Office Action dated January 21, 2003. The three-month period for response expired April 21, 2003. The PAIR system indicates the PTO received the response on May 27, 2003, thereby according an Applicant Delay of 36 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an unwarranted mail delay and that the correct Applicant Delay is 35 days, as outlined further below.
4. Applicants submitted a response on September 17, 2003, to the final Office Action dated July 21, 2003. The three-month period for response expired on October 21, 2003. The PAIR system indicates the PTO received Applicants' response on November 20, 2003, thereby according an Applicant Delay of 30 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 0 days, as outlined further below.
5. Applicants submitted a Request for Continued Examination (RCE) on March 8, 2004, in response to the Notice of Allowance issued December 9, 2003. The

three-month period for response expired on March 9, 2004. The PAIR system indicates the PTO received the paper on March 11, 2004. No Applicant Delay was accorded. In good faith and candor, Applicants submit that the PTO may wish to consider according 2 days of Applicant Delay for late receipt of Applicants' response to the Notice of Allowance.

6. The PTO calculates a total PTO Delay of 439 days and a total Applicant Delay of 127 days, for a total PTA of 312 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct total Applicant Delay is 37 days, thus yielding a total PTA of 402 days.

## **II. CALCULATION OF APPLICANT DELAY**

### **A. Applicant Delay Should Not Be Calculated from March 29, 2002, as Timely Response Was Made and Notice of Incomplete Application Was Vacated**

On March 29, 2002, the PTO mailed a Notice of Incomplete Nonprovisional Application (copy enclosed) requesting a newly signed inventors' oath or declaration, the missing parts surcharge fee, and drawings. Applicants responded to the Notice on May 28, 2002, by submitting a Petition Under 37 CFR §§1.17(h), 1.53(e), and 1.181 to Accord Filing Date (copy enclosed). The PAIR system indicates the Petition was received in a timely manner, as it was received and entered on June 6, 2002. The three-month period for response did not expire until June 29, 2002.

In its Decision on Petition mailed August 19, 2002 (copy enclosed), the PTO indicates that "the 29 March, 2002, 'Notice of Incomplete Nonprovisional Application' hereby is vacated." The application was not marked as "complete" in the PAIR system until August 29, 2002. As Applicant Delay is calculated until the application is "complete," Applicants were unduly accorded with a total delay of 61 days.

Thus, Applicants respectfully request correction of the "Application is Now Complete" entry in the PAIR system to be dated not later than June 6, 2002. Applicants also request correction of the PTA calculation to remove all Applicant Delay associated with the response to the Notice of Incomplete Nonprovisional Application mailed March 29, 2002.

**B. Postal Service Delays Should Be Limited When Calculating Applicant Delay for Response to Non-Final Office Action Dated January 21, 2003**

On May 21, 2003, Applicants mailed a response to the Non-Final Office Action dated January 21, 2003. The PAIR system indicates the PTO received Applicants' response on May 27, 2003. As the three-month period for response expired on April 21, 2003, Applicants were thus accorded an Applicant Delay of 36 days for late response to the outstanding action.

As indicated in the Official Gazette Notice dated January 15, 2002 (copy enclosed),

"If a reply to an Office action or notice was mailed on or after October 13, 2001 and no later than December 1, 2001 (as shown on a certificate of mailing under 37 CFR 1.8), and the applicant is otherwise entitled to patent term adjustment (or additional patent term adjustment) but for the fact that there was a reduction of such patent term adjustment under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b) due to the receipt of such reply by the Office more than three business days after the date indicated on the certificate of mailing, the Office will consider the USPS mail situation discussed in this notice to constitute a sufficient showing that, in spite of all due care, the applicant was unable to reply to the Office action or notice within three months of the date of mailing of the Office action or notice."

Though this Notice specifically references the historical time period and events surrounding September 11, 2001, Applicants respectfully submit that the timeframe for postal delays indicated by the Notice – three business days – is suggestive of the PTO's view of an acceptable postal service delay.

Applicants therefore respectfully request that the present response be considered received not later than May 26, 2003 (three business days after its mailing date according to the certificate of mailing date of May 21, 2003). Entry of this receipt date would thus accord Applicant a delay of 35 days, as the three-month deadline for response to the Office Action mailed January 21, 2003, was April 21, 2003.

**C. Applicants' Response to the Final Office Action Dated July 21, 2003, Was Complete and Timely**

On July 21, 2003, the PTO mailed a final Office Action. Applicants mailed a Response to the outstanding action (copy enclosed) on September 17, 2003. The PAIR system does not indicate that the PTO received Applicants' response; however, a return receipt postcard was received (copy enclosed) with the PTO's date stamp of September 22, 2003. At the Examiner's

request, Applicants resubmitted the response via facsimile on November 20, 2003 (copy enclosed).

The original response was never entered into the PAIR system, and Applicant Delay was calculated until receipt of the resubmitted response on November 20, 2003. As the PTO received Applicants' complete response within the three-month window for response to the outstanding action, Applicants should not be assessed any delay for the response to this Notice. Applicants thus respectfully request removal of the 30 days of Applicant Delay assessed for late response to this action.

**D. In Good Faith and Candor, Applicants Submit That The Office May Wish to Recalculate Applicant Delay With Respect to the RCE Filed March 8, 2004**

The Office mailed a Notice of Allowance on December 9, 2003. Applicants' response was due in the Office not later than March 9, 2004. As Applicants filed their RCE via first class mail on March 8, 2004, and it was not received in the Office until March 11, 2004, the Office may wish to consider assessing two days of Applicant Delay for a late response to the Notice of Allowance.

**III. DOCUMENTS ENCLOSED**

A copy of each of the following documents is provided herein:

- 1) Notice of Allowance mailed July 9, 2004;
- 2) Notice of Incomplete Application mailed March 29, 2002;
- 3) Petition Under 37 CFR §§1.17(h), 1.53(e), and 1.181 to Accord Filing Date dated May 28, 2002, and PTO date-stamped postcard indicating receipt date of June 6, 2002;
- 4) Decision on Petition dated August 19, 2002;
- 5) Official Gazette Notice dated January 15, 2002;
- 6) Amendment and Reply to Office Action Dated July 21, 2004, mailed September 17, 2003, and PTO date-stamped postcard indicating receipt date of September 22, 2003;

- 7) Facsimile Resubmission of Amendment and Reply to Office Action Dated July 21, 2004, dated November 20, 2004; and,
- 8) Transmittal of Request For Continued Examination dated March 8, 2004, and PTO date-stamped postcard indicating receipt date of March 11, 2004.

#### **IV. REMARKS**

In consideration of the events described above, Applicants believe the PTA calculation of 312 days is incorrect. Applicants respectfully request recalculation of the patent term adjustment in the following manner:

- 1) Total PTO Delay should be calculated as 439 days (for a delayed first non-final Office Action); and
- 2) Total Applicant Delay should be calculated as 37 days (35 days for delayed response to non-final Office Action; 2 days for delayed response to Notice of Allowance).

Therefore, Applicants respectfully request the removal of 90 days of Applicant Delay, thus decreasing Applicant Delay from 127 days to 37 days and increasing the Total PTA from 312 to 402 days.

Applicants also kindly request correction of the file history in the PAIR system to indicate receipt of its response dated September 17, 2003, and to indicate that the Notice of Incomplete Nonprovisional Application was vacated by the Office.

Applicant : Randall B. Lauffer et al.  
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Filed : September 8, 2000  
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Attorney's Docket No.: 13498-009002 / MET-7/Continuation

Enclosed is a check for the fee of \$200 required under 37 CFR §1.18(e). Please apply any other required charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 10/6/04

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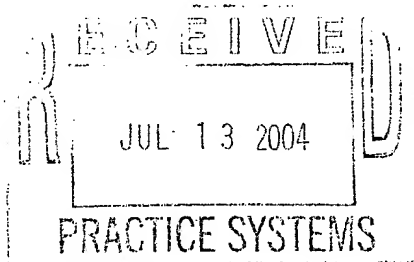


# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 07/09/2004  
FISH & RICHARDSON P.C.  
3300 DAIN RAUSCHER PLAZA  
60 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402



EXAMINER	
HARTLEY, MICHAEL G	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/09/2004

13498-009002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,706	09/08/2000	Randall B. Lauffer	MET/7 CON	3760

TITLE OF INVENTION: CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR MONITORING INTERVENTIONAL THERAPIES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$665	\$0	\$665	10/12/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



This application contains method claims, e.g., claims 36 - 63. Therefore, the application should have been treated as an application filed without all of the drawing figures referred to in the specification as discussed in MPEP §601.01(g).<sup>5</sup>

It appears that a "Notice of Omitted Items" should have been mailed instead of the "Notice of Incomplete Nonprovisional Application."

Therefore, the 29 March, 2002, "Notice of Incomplete Nonprovisional Application" hereby is vacated.

The application is accorded a filing date of 8 September, 2000.

The petition is granted in part, to the extent that the application will be accorded the filing date of 8 September, 2000, without the drawings containing Figures 1 - 3 as part of the original disclosure of the application.

**The application file is being returned to the Office of Initial Patent Examination for further processing with a corrected filing date of 8 September, 2000, indicating in the Office records that "0" sheets of drawings were present on filing, and the mailing of a corrected filing receipt.**

The Revocation and Power of Attorney filed 20 May, 2002, hereby is acknowledged and accepted.

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USPTO.

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<sup>5</sup> The commentary at MPEP §601.01 provides in pertinent part:

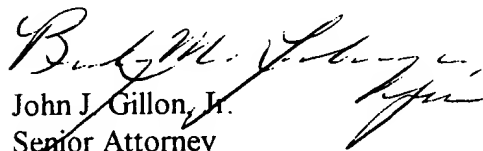
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**601.01(g) Applications Filed Without All Figures of Drawings**

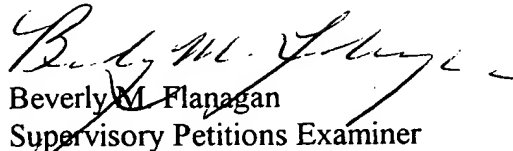
The Office of Initial Patent Examination (OIPE) reviews application papers to determine whether all of the figures of the drawings that are mentioned in the specification are present in the application. If the application is filed without all of the drawing figure(s) referred to in the specification, and the application contains something that can be construed as a written description, at least one drawing, if necessary under 35 U.S.C. 113 (first sentence), and, in a nonprovisional application, at least one claim, OIPE will mail a "Notice of Omitted Item(s)" indicating that the application papers so deposited have been accorded a filing date, but are lacking some of the figures of drawings described in the specification. The mailing of a "Notice of Omitted Item(s)" will permit the applicant to either: (1) promptly establish prior receipt in the USPTO of the drawing(s) at issue (generally by way of a date-stamped postcard receipt (MPEP § 503)); or (2) promptly submit the omitted drawing(s) in a nonprovisional application and accept the date of such submission as the application filing date. An applicant asserting that the drawing(s) was in fact deposited in the USPTO with the application papers must, within 2 months from the date of the "Notice of Omitted Item(s)," file a petition under 37 C.F.R. 1.53(e) with the petition fee set forth in 37 C.F.R. 1.17(h), along with evidence of such deposit (37 C.F.R. 1.181(f)). The petition fee will be refunded if it is determined that the drawing(s) was in fact received by the USPTO with the application papers deposited on filing.

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Telephone inquiries concerning this matter may be directed to John J. Gillon, Jr., Senior Attorney, Office of Petitions, at (703)305-9199.



John J. Gillon, Jr.  
Senior Attorney  
Office of Petitions  
Office of the Deputy Commissioner  
for Patent Examination Policy



Beverly M. Flanagan  
Supervisory Petitions Examiner  
Office of Petitions  
Office of the Deputy Commissioner  
for Patent Examination Policy

## United States Patent and Trademark Office OG Notices: 15 January 2002

### Processing of, and Requirements for, the Filing of Duplicate Applications and Papers in Patent Applications in view of USPS Mail Delays

Although mailed correspondence is being received by the United States Patent and Trademark Office (USPTO or Office), many papers that were mailed by first class mail or Express Mail through the United States Postal Service (USPS) in October and November of 2001 have had their delivery delayed. See Mitigation of Delays in Mail Deliveries to the USPTO, which is posted on the USPTO Internet Web site at:

<http://www.uspto.gov/september11/mitigationofmaildelays.htm>.

Some of those papers still have not been received by the USPTO. Although the USPS reports ([http://www.usps.com/news/2001/press/pr01\\_1023fact.htm](http://www.usps.com/news/2001/press/pr01_1023fact.htm)) that "98% of mail at the Brentwood facility has been sanitized and delivered," the USPS has also informed the USPTO that some of the mail that was in the Brentwood Mail facility on October 21 or 22, 2001 may never be received by the USPTO because of anthrax-related decontamination activities. Some applicants, concerned about papers mailed during this time period that have not been received by the USPTO, have filed duplicate copies of the original correspondence along with a statement that meets the requirement in 37 CFR 1.8(b)(3) prior to any holding of abandonment to permit the Office to more timely act on the correspondence. While Office processing of such duplicates will enable the examination process to move forward, applicants should be aware that the submission of duplicate copies may be unnecessary (and could slow down the processing of the application) and that double charging (collection) of the fees may result from subsequent processing by the Office of the delayed original, which may lead to the submission for, and the processing of, refund requests. The Office will try, however, to avoid double charging (collection) of fees as much as is possible.

#### I. Timeliness of Replies Whose Delivery to the Office has been Delayed:

In accordance with the Office's usual practice, if a paper was mailed with a certificate of mailing, the Office will determine the timeliness (e.g., 35 U.S.C. 133) of the paper based on the certificate of mailing date as set forth in 37 CFR 1.8(a). See Manual of Patent Examining Procedure (MPEP), Eighth Edition, 512, (August 2001). If a paper was sent by Express Mail, the Office will determine the timeliness and filing date of the paper based on the date of deposit with the USPS, which is the "date-in" on the Express Mail mailing label as set forth in 37 CFR 1.10(a). See MPEP 513. Therefore, if the procedures under 37 CFR 1.8 or 1.10 have been followed, any delays in delivery of the paper to the Office will not impact the timeliness of the paper. The Office will process a reply (whose delivery to the Office has been delayed) as timely if the date on the certificate of mailing, or the "date-in" on the Express Mail mailing label, is within the period for reply set forth in the prior Office action or notice.

#### II. Timeliness of Duplicate Replies Filed when the Original has not been Received by the Office:

A. If the duplicate is, itself, timely filed: If applicant submits a duplicate copy of a paper that has not been received in the Office, the duplicate paper will be processed by the Office as timely if the duplicate

is filed within the period for reply to the prior Office action or notice (not considering any extensions of time that may have been available).

B. If a duplicate is filed after the expiration of reply period but with acceptable proof of prior timely filing: If the original reply was timely mailed within the period from October 13, 2001 to December 1, 2001 using the certificate of mailing procedure under 37 CFR 1.8, and a duplicate copy is received in the Office after the period for reply has expired, then the Office shall accept the duplicate as the reply, and to have been timely filed, if applicant submits:

(1) a copy of the previously mailed reply and certificate of mailing of the previously mailed reply (the certificate of mailing must be signed and the certificate of mailing must itself indicate the date of mailing); and

(2) a statement that the reply was previously mailed to the USPTO on the date indicated on the certificate of mailing.

It is not sufficient to stamp the reply "Duplicate" or "Copy" and to fax the document to the USPTO, a statement is always required. The statement can be part of the fax transmittal cover sheet or the cover letter so long as the fax transmittal sheet is signed as specified below. The statement must be signed by: the person who personally mailed the original reply, a registered patent attorney or agent, the assignee of the entire interest, or the applicant (all of the inventors or the party qualified under 37 CFR 1.42, 1.43 or 1.47). For example, the statement may be: "This is a copy of correspondence that was mailed to the USPTO on \_\_\_\_\_ date" or "This is a copy of an amendment that was mailed to the USPTO on the date of the certificate of mailing."

If a certificate of mailing as set forth in 37 CFR 1.8 was not used (or if the certificate of mailing was not signed, or if the certificate of mailing did not include a date), and applicant does not have a post card receipt for the correspondence, the Office cannot accord the duplicate correspondence any date other than the date that the duplicate was actually received in the Office. If the duplicate copy was not itself timely filed, applicant should consider filing a petition to revive under 37 CFR 1.137(a) or (b).

To the extent that this treatment of showings as set forth 37 CFR 1.8(b) (3) is less stringent than the requirements set forth in 37 CFR 1.8(b) (3), the provisions of 37 CFR 1.8(b) (3) are hereby sua sponte waived for replies mailed on or after October 13, 2001 and no later than December 1, 2001.

### III. Establishing that a Paper other than a Reply was Mailed to the USPTO

A paper that is not a reply to an Office action or is not a correspondence that is required to be filed in the USPTO within a set period of time is NOT entitled to the benefit of a certificate of mailing under 37 CFR 1.8(a). The filing date of such a paper is the actual date of receipt in the USPTO, except as provided by 37 CFR 1.10. For example, a preliminary amendment is not a reply to an Office action and, therefore, would not receive the benefit of a certificate of mailing under 37 CFR 1.8(a). On the other hand, an information disclosure statement (IDS) will be considered to have been filed on the "date that it was received in the Office, or an earlier date of mailing if accompanied by a properly executed certificate of mailing." See MPEP 609, page 600-124. An IDS is entitled

to the benefit of a certificate of mailing under 37 CFR 1.8(a) since the IDS is a correspondence that is required to be filed in the USPTO within a set period of time. To establish that a paper not entitled to the benefit of a certificate of mailing under 37 CFR 1.8(a) was filed in the USPTO, applicant must have used Express Mail and comply with the provisions of 37 CFR 1.10, or have a post card receipt establishing that the paper was actually received in the USPTO. Other than in these circumstances, the rules do not provide a mechanism for establishing that such a paper was filed in the USPTO.

#### IV. Office Will Try to Call Before Abandoning Applications Without a Reply:

In most circumstances, before holding an application to be abandoned, staff from the Technology Centers and the Office of Patent Publication will attempt to call applicants to see if a reply has been previously filed. If a reply has been filed, applicant will be requested to fax (or file) a duplicate copy of the prior (original) paper along with a showing as set forth in 37 CFR 1.8(b)(3) in order to avoid the application from being held abandoned.

If applicant files a duplicate with an acceptable showing as set forth in 37 CFR 1.8(b)(3), it will avoid both the Office holding the application as abandoned, and the processing delays associated with the withdrawal of such abandonment.

#### V. Duplicate Fee Charges (Collections) are Possible When Duplicates are Filed:

When the Office is processing a duplicate before processing the original, the Office shall charge (collect) all fees that are due for the proper processing of the paper, and will not process any papers that are not accompanied by the appropriate fee. Accordingly, applicants should expect that the same fees may inadvertently be charged (collected) when the Office later processes the original paper. The Office will try to avoid this type of double charging (collecting) by checking to see if the fees required to process a delayed original paper were previously charged (collected) and, if previously charged (collected), the Office will not charge (collect) the fees a second time. The Office, however, cannot guarantee that double charging (collecting) will not occur. If the Office processes fees with both the duplicate and then the original papers, applicant may request a refund under 37 CFR 1.26. If the application has been allowed, the refund request should be filed after the patent has been issued in order to avoid printing delays. When the original paper corresponding to the duplicate is received, the original paper will be attached to the duplicate in the application file wrapper and will not be listed as a separate contents entry for the application in the Office's records. This procedure will be used notwithstanding the procedure set forth in MPEP 719.01(a).

#### VI. How to File a Duplicate Reply during Examination or after Allowance:

A. If the Application is in a Technology Center: If applicant desires to file a duplicate copy of a reply to an Office action, with an appropriate showing as set forth in 37 CFR 1.8(b)(3), the duplicate should be faxed to the appropriate Technology Center. The reply facsimile numbers for each Technology Center that should be used are posted on the USPTO Internet web site at: <http://www.uspto.gov/september11/faxnotice.htm>.

B. If the Application has been Allowed: If applicant desires to file a

duplicate Issue Fee transmittal (e.g., a duplicate PTOL-85B) in order to pay the issue fee and any publication fee, along with a duplicate copy of other post allowance correspondence that was submitted with the issue fee transmittal, accompanied by an appropriate showing as set forth 37 CFR 1.8(b)(3), the duplicate submission(s) and the showing(s) should be faxed to Box Issue Fee: (703) 746-4000. If an amendment under 37 CFR 1.312 was mailed before payment of the issue fee, and the Office has not yet received the amendment, applicant should include a copy of the amendment (and a statement explaining when the amendment was filed) with the issue fee payment so that the amendment under 37 CFR 1.312 is not treated as having been filed after payment of the issue fee, and therefore not entered (because amendments after payment of the issue fee are no longer permitted).

#### VII. Filing of Duplicate New Applications and Replies to OIPE:

The USPTO appreciates, that, where warranted, applicants should take advantage of 37 CFR 1.8(b) and 1.10(e), which permits the filing of duplicate copies of prior correspondence in place of lost or missing originals. While applicants should, as a general rule, promptly file a duplicate (of a new application filing or a reply to an OIPE notice) when they become aware that the Office has not received, and may not ever receive, an item of correspondence, the level of urgency usually associated with such action should take into account the fact that the USPTO expects to receive all, or substantially all, of the delayed correspondence. In addition, correspondence will be treated as filed (37 CFR 1.10) or timely (37 CFR 1.8), if applicant originally filed under those provisions regardless of the length of time that the correspondence took to reach the Office. In the event the Office has not received the original by March 1, 2002 applicant then should file a duplicate. The Office will mail a return post card receipt and/or filing receipt or notice, as it usually does, when correspondence is received by the Office so applicant will be informed when delayed correspondence has been received.

When the USPTO receives a duplicate submission, it shall consider a showing that a reply was timely mailed as set forth 37 CFR 1.8(b), or a petition for a filing date under 37 CFR 1.10(e), to have been timely filed so long as the showing or petition is filed by May of 2002. To the extent that this standard for timeliness is less stringent than the requirements set forth in 37 CFR 1.8(b)(1), 1.10(e)(1) and 1.181(f), the provisions of 37 CFR 1.8(b)(1), 1.10(e)(1) and 1.181(f) are hereby sua sponte waived for applications and papers mailed on or after October 13, 2001 and no later than December 1, 2001. Where there is a special need, however, applicants should take advantage of the rules and file duplicates without delay. Special needs could include the following: applications and correspondence mailed on or after October 17, and before October 23, 2001 that have not yet been received by the Office, Patent Cooperation Treaty application filings where priority has been claimed, design applications, replies to a Notice of Incomplete Application (filing date not granted) which was mailed under 37 CFR 1.8, and where certified copies of an application will be needed for priority purposes. In all other situations, before filing a duplicate of a prior mailed correspondence pursuant to 37 CFR 1.8(b) and 1.10(e), applicants might want to wait to see if the original is later received.

If correspondence sent via Express Mail was returned to applicant by the USPS, applicants should not file a duplicate, and should instead mail the original correspondence back to the USPTO as described in the notice "Suspension of the 'Express Mail' Service of

United States Postal Service for mail addressed to ZIP Codes 202xx through 205xx" that is posted on the USPTO Internet Web site at: <http://www.uspto.gov/september11/uspsmaildisrup.htm>.

Applicants who did not file an application using Express Mail may wish to consider filing a duplicate copy of the application via Express Mail, and not including the basic filing fee, or an authorization to charge the basic filing fee to a deposit account. When a duplicate application is submitted, applicant should anticipate that the duplicate (copy) application will be processed as a new application, any fees due will be attempted to be collected (as by either charging a deposit account if an authorization is given, or by mailing a Notice to File Missing Parts, requiring the filing fee(s)), and a filing receipt mailed. If the filing date accorded to the duplicate copy is an earlier filing date than that accorded the application that was previously mailed by first class mail, then applicant should respond to the Notice to File Missing Parts and pay the basic filing fee. If the application that was previously mailed by first class mail is given a filing date before that of the duplicate, applicant need not reply to the Notice to File Missing Parts in the duplicate application, and can just prosecute the original application (thereby allowing the later-filed duplicate application to go abandoned).

When applicant mails a reply to a Notice from OIPE using a certificate of mailing, the reply will be considered to be timely so long as the certificate of mailing was dated before the due date set in the Notice, regardless of the length of time that it took to reach the USPTO. If the date of receipt of the correspondence was important, and applicant did not use Express Mail, and the response has not yet been received, applicant may wish to file a duplicate copy of the reply by Express Mail. An example of such a situation would be where a reply to a Notice of Omitted Items included a copy of a missing page of specification and requested a filing date of the date of receipt of the page of specification. The duplicate correspondence mailed to the Office pursuant to the Express Mail provisions of 37 CFR 1.10 will be given a filing date of the "date in" accorded by the USPS. If the duplicate is faxed to OIPE, the correspondence will be given a filing date as of the date of receipt, or if the actual date of receipt is a Saturday, Sunday or Federal Holiday, the next business day (see 37 CFR 1.6(a)(3)).

At the present time applications held in OIPE that are awaiting replies will not be processed as abandoned (if a reply could have been timely made during this period of delayed mail) and, therefore, calls requesting applicants to submit duplicate copies of replies to such notices will not generally be made. Calls to request such papers may be made for design applications.

#### VIII. Patent Term Adjustment:

Applications filed on or after May 29, 2000 may be eligible for patent term adjustment if issue of the patent has been delayed due to the failure of the Office to meet one of the time periods set forth in 35 U.S.C. 154(b)(1). See 35 U.S.C. 154(b). 37 CFR 1.703(f) provides that the date indicated on any certificate of mailing or transmission under 37 CFR 1.8 is not taken into account in a patent term adjustment calculation. If a reply to any Office action or notice is filed more than three months after the mailing date of the Office action or notice, the period between the date that is three months after the mailing date of the Office action or notice and the date of receipt (37 CFR 1.6) of the reply is considered a failure to engage in

reasonable efforts to conclude prosecution, and any patent term adjustment to which the applicant would otherwise be entitled is required to be reduced by this period. See 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b). 35 U.S.C. 154(b)(3)(C) and 37 CFR 1.705(c), however, provide that an applicant may request reinstatement of all or part of the period of adjustment reduced pursuant to 35 U.S.C. 154(b)(2)(C) and 37 CFR 1.704(b) for failing to reply to an Office action or notice within three months of the date of mailing of the Office action or notice if the applicant provides a showing that, in spite of all due care, the applicant was unable to reply to the Office action or notice within three months of the date of mailing of the Office action or notice, but 35 U.S.C. 154(b)(3)(C) does not permit the Office to grant any request for reinstatement for more than three additional months for each reply beyond three months from the date of mailing of the Office action or notice.

If a reply to an Office action or notice was mailed on or after October 13, 2001 and no later than December 1, 2001 (as shown on a certificate of mailing under 37 CFR 1.8), and the applicant is otherwise entitled to patent term adjustment (or additional patent term adjustment) but for the fact that there was a reduction of such patent term adjustment under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b) due to the receipt of such reply by the Office more than three business days after the date indicated on the certificate of mailing, the Office will consider the USPS mail situation discussed in this notice to constitute a sufficient showing that, in spite of all due care, the applicant was unable to reply to the Office action or notice within three months of the date of mailing of the Office action or notice. In this situation, the Office will, subject to the conditions set forth below, reinstate a period equal to the period beginning on the date that is four business days after the date indicated on the certificate of mailing on the reply and the date of receipt (37 CFR 1.6) of the reply in the Office up to a maximum of three months.

If an applicant's request for reinstatement of patent term adjustment for the reason set forth above is the sole basis for requesting a change to the patent term adjustment indicated on the notice of allowance, the Office will waive the requirements of 37 CFR 1.705 (including fees) if the applicant submits a request for reinstatement of patent term meeting the following conditions:

(1) The request is submitted no later than the payment of the issue fee but no earlier than the date of mailing of the notice of allowance (unless the paper that was delayed in the mail was the issue fee payment or other paper submitted with or after payment of the issue fee, in which case the request must be submitted as soon as possible but no later than the day before the date of issue of the patent).

(2) The request is transmitted by facsimile to the Office of Petitions at (703)308-6916.

(3) The request includes:

(a) a copy of the part of page with the certificate of mailing under 37 CFR 1.8 and a description of the paper (e.g., amendment, issue fee transmittal, notice of appeal);

(b) the date of receipt in the Office of the paper; and (c) the number of days requested to be reinstated as a result of the USPS mail situation discussed in this notice.

In addition, if applicant has access to the Patent Application



Information Retrieval (PAIR) system, a copy of the PAIR contents records with the entry highlighted should also be included.

Applicants are again reminded that to maximize patent term adjustment they may wish to consider filing replies to Office actions: (1) under the "Express Mail" provisions of 37 CFR 1.10; (2) by facsimile; or (3) by hand-delivery. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56366, 56376 (Sept. 18, 2000), 1239 Off. Gaz. Pat. Office 14, 22-23 (Oct. 3, 2000) (final rule) (response to comment 10).

#### IX. Contact Information:

If you have a question relating to the status of a reply for an application in a Technology Center, please contact the Customer Service Representative of that Technology Center. If you have a question relating to the receipt of a new application or a reply for an application in OIPE, please contact the Customer Service Center in OIPE at (703) 308-1202. If you have a question relating to the receipt of post allowance correspondence, including issue and publication fee payments, please contact the Customer Service Center of the Office of Publications at (703) 305- 8283.

Questions concerning this notice should be directed to Darnell Jayne, Legal Advisor, Office of Patent Legal Administration at (703) 308-6906.

December 20, 2001

ROBERT SPAR for  
STEPHEN G. KUNIN  
Deputy Commissioner for  
Patent Examination Policy



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Randall B. Lauffer et al.                      Art Unit : 1619  
Serial No. : 09/887,706                                      Examiner : M. Hartley  
Filed : September 8, 2000  
Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT AND REPLY TO ACTION DATED JULY 21, 2003

In response to the action dated July 21, 2003, please amend the application as follows:

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 17, 2003

Date of Deposit

Angela J. Montgomery

Signature

Angela J. Montgomery

Typed or Printed Name of Person Signing Certificate

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1.-63. (Cancelled).

64. (Currently Amended) A method for monitoring treatment of a tissue comprising HSA in a patient, said method comprising:

a) administering a contrast agent to said patient, ~~said contrast agent comprising an organic chelating agent complexed to a paramagnetic metal ion, wherein said contrast agent is selected from the group consisting of MS-315, MS-317, MS-322, MS-323, MS-325, MS-326, MS-327, and MS-328;~~

~~— wherein said organic chelating agent is selected from the group consisting of DTPA, DOTA, DTPA-BMA, and HP-DO3A;~~

~~— wherein said organic chelating agent is covalently bound to a structure: (L)<sub>m</sub>-SDTBM either at a methyl carbon of an acetate chelating moiety of said organic chelating agent or at an ethylene carbon backbone moiety of said organic chelating agent,~~

~~wherein L is a physiologically compatible linker and wherein m can be 0 to 4;~~

~~wherein said SDTBM comprises zero to six linear or branched alkyl groups having 1 to 10 carbon atoms; zero one to five cycloalkyl groups; zero to five aryl groups; or combinations thereof, wherein said alkyl, cycloalkyl, or aryl groups can be optionally and independently substituted with from 1 to 5 ether, carboxylate, or sulfate moieties~~

~~said contrast agent further having:~~

~~1) an R1 observed value in a 4.5 wt% solution of HSA at 25 °C of greater than about  $10 \text{ mM}^+ \text{ sec}^+$ ; and~~

~~2) a percent binding to HSA in a 4.5 wt%, pH 7.4 solution of HSA of greater than about 10%;~~

b) subjecting said patient to magnetic resonance imaging to determine an initial signal intensity value in a region of interest of said undesired tissue;

c) applying an interventional therapy to at least a portion of said undesired tissue in order to treat said undesired tissue, said interventional therapy selected from the group consisting of a thermal energy generation, a cryoablation, an injection of a denaturing liquid, an injection of a chemotherapeutic agent, and a photodynamic therapy; and

d) contemporaneously monitoring with magnetic resonance imaging a change in said initial signal intensity value in said region of interest of said undesired tissue during said interventional therapy; and

~~e) stopping said interventional therapy application when said change in said initial signal intensity value in said region of interest of said undesired tissue is more than about a 10% reduction in said initial signal intensity value.~~

65.-78. (Cancelled).

79. (Previously Presented) The method of claim 64, wherein said tissue is selected from the group consisting of cancerous tissue, tumorous tissue, and neoplastic tissue.

80. (Previously Presented) The method of claim 79, wherein said tissue is cancerous tissue.

81. (Previously Presented) The method of claim 64, wherein said interventional therapy application is said generation of thermal energy, and wherein said thermal energy is

generated by a source selected from the group consisting of one or more focused ultrasound waves, radiofrequency waves, microwaves, and lasers.

82.-84. (Cancelled).

85. (New) The method of claim 64, further comprising:

e) stopping said interventional therapy application when said change in said initial signal intensity value in said region of interest of said undesired tissue is more than about a 10% reduction in said initial signal intensity value.

### REMARKS

Claims 64, 65, 67, and 71-84 were pending. The Examiner rejected claims 64, 65, 67, and 71-84. Applicants have herein amended claim 64, cancelled claims 65, 67, 71-78, and 82-84, and added claim 85. Amendments to claim 64 find support in prior claim 83 and at page 42 of the specification. New claim 85 finds support in prior claim 64. Accordingly, no new matter has been added. Thus, claims 64, 79-81, and 85 are pending.

Applicants thank the Examiner for the courtesy of the telephonic interview on September 16, 2003 to discuss the pending claims. In light of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of claims 64, 79-81, and 85.

#### Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 64, 65, 67, and 71-84 under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner stated that there was no structural relationship of elements making up the SDTBM.

Applicants respectfully disagree. The prior claims did provide a structural arrangement of the elements making up the SDTBM, as set forth more fully in the Response to Office Action filed May 21, 2003. In order to expedite prosecution, however, Applicants have herein amended claim 64 to recite the contrast agents set forth in prior claim 83. Chemical structures for the contrast agents can be found on page 42 of the specification. Accordingly, present claim 64 does provide essential structural relationships for the contrast agents to be used in the method.

Given the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

#### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner also rejected claims 64, 65, 67, and 71-84 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner stated

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 6 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

that the specification failed to describe the SDTBM as comprising "zero to six linear or branched alkyl groups having 1 to 10 carbon atoms; zero to five cycloalkyl groups, zero to five aryl groups."

Applicants respectfully disagree. As indicated more fully in the Response to Office Action filed May 21, 2003, the specification does provide written description for the SDTBM as previously claimed. In order to expedite prosecution, however, Applicants have herein amended claim 64 to recite the contrast agents set forth in prior claim 83. Support for the structure of the contrast agents can be found at page 42 of the specification. Accordingly, present claim 64 does have adequate written description in the specification.

Given the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

#### CONCLUSION

In light of the amendments and remarks herein, Applicants respectfully request allowance of claims 64, 79-81, and 85. The Examiner is invited to call the under-signed attorney if such would expedite prosecution.

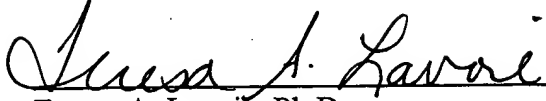
No fees are believed due. Please apply any other charges or credits to deposit account 06-1050.

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 7 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

Respectfully submitted,

Date: 9/17/03

  
Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

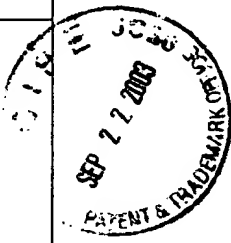
Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

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TAL

Attorney's Docket No. 13498-009002	Express Mail Label No.	Mailing Date September 17, 2003	<b>For PTO Use Only</b> <i>Do Not Mark in This Area</i>
Application No. 09/887,706	Filing Date September 8, 2000	Attorney/Secretary Init MSE/TAL/ajm	
Title of the Invention CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR MONITORING INTERVENTIONAL THERAPIES			
Applicant Randall B. Lauffer et al.			
Client Reference No. MET-7/Continuation			
Enclosures Amendment/Response (7 pages)			



ajm



Attorney's Docket No.: 13498-009002  
Client's Ref. No.: MET-7/Con.

## OFFICIAL COMMUNICATION

### FACSIMILE

**U.S. PATENT AND TRADEMARK OFFICE (PATENT)**

**ASSISTANT COMMISSIONER OF PATENTS**

**WASHINGTON, D.C. 20231**

**GROUP 1616 FAX NO: 1-703-308-4556**

Number of pages including this page 10

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000

Art Unit : 1616  
Examiner : Michael Hartley

### FACSIMILE COMMUNICATION

Title : Contrast-Enhanced Diagnostic Imaging Method for Monitoring Interventional Therapies

### MAIL STOP AF

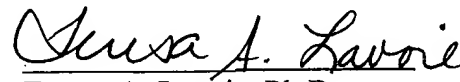
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Attached to this facsimile communication cover sheet are copies of a return receipt postcard, an Amendment and Reply (mailed September 17, 2003) and a Letter, faxed this 20<sup>th</sup> day of November, 2003, to Group 1616, the United States Patent and Trademark Office.

Respectfully submitted,

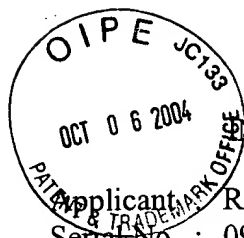
Date: November 20, 2003

  
Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Fax: (612) 288-9696

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**NOTE: This facsimile is intended for the addressee only and may contain privileged or confidential information. If you have received this facsimile in error, please immediately call us collect at (612) 335-5070 to arrange for its return. Thank you.**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Randall B. Lauffer et al. Art Unit : 1616  
Serial No. : 09/887,706 Examiner : Michael G. Hartley  
Filed : September 8, 2000  
Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

**MAIL STOP AF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

LETTER

Pursuant to a telephone conference today with Examiner Hartley, enclosed is a copy of the Amendment and Reply to the **FINAL** office action, said **FINAL** action mailed July 21, 2003, in the above-referenced case, said Amendment and Reply mailed September 17, 2003, along with a copy of the return receipt postcard with a stamp from OIPE indicating that the Amendment and Reply was received September 22, 2003. This Amendment and Reply has not been matched with the file and this is a courtesy copy to be matched and forwarded to Examiner Hartley for review.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: November 20, 2003

Teresa A. Lavoie

Teresa A. Lavoie, Ph.D.

Reg. No. 42,782

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

60179397.doc

CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date indicated below.

November 20, 2003

Date of Transmission

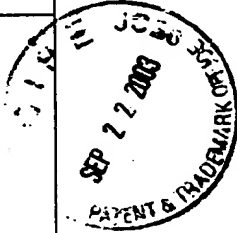
Signature

Angela J. Montgomery

Typed or Printed Name of Person Signing Certificate

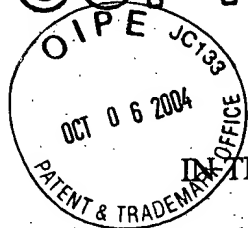
TAL

COPY

Attorney's Docket No. 13498-009002	Express Mail Label No.	Mailing Date September 17, 2003	<b>For PTO Use Only</b> <i>Do Not Mark in This Area</i>
Application No. 09/887,706	Filing Date September 8, 2000	Attorney/Secretary Init MSE/TAL/ajm	
Title of the Invention CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR MONITORING INTERVENTIONAL THERAPIES			
Applicant Randall B. Lauffer et al.			
Client Reference No. MET-7/Continuation			
Enclosures Amendment/Response (7 pages)			

ajm

COPY



Attorney's Docket No.: 13498-009002 / MET-7/Continuation

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Randall B. Lauffer et al.

Art Unit : 1619

Serial No. : 09/887,706

Examiner : M. Hartley

Filed : September 8, 2000

Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT AND REPLY TO ACTION DATED JULY 21, 2003

In response to the action dated July 21, 2003, please amend the application as follows:

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 17, 2003

Date of Deposit

Angela J. Montgomery

Signature

Angela J. Montgomery

Typed or Printed Name of Person Signing Certificate

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1.-63. (Cancelled).

64. (Currently Amended) A method for monitoring treatment of a tissue comprising HSA in a patient, said method comprising:

a) administering a contrast agent to said patient, ~~said contrast agent comprising an organic chelating agent complexed to a paramagnetic metal ion, wherein said contrast agent is selected from the group consisting of MS-315, MS-317, MS-322, MS-323, MS-325, MS-326, MS-327, and MS-328;~~

~~wherein said organic chelating agent is selected from the group consisting of DTPA, DOTA, DTPA-BMA, and HP-DO3A;~~

~~wherein said organic chelating agent is covalently bound to a structure:  $(L)_m$ -SDTBM either at a methyl carbon of an acetate chelating moiety of said organic chelating agent or at an ethylene carbon backbone moiety of said organic chelating agent;~~

~~wherein L is a physiologically compatible linker and wherein m can be 0 to 4;~~

~~wherein said SDTBM comprises zero to six linear or branched alkyl groups having 1 to 10 carbon atoms; zero one to five cycloalkyl groups; zero to five aryl groups; or combinations thereof, wherein said alkyl, cycloalkyl, or aryl groups can be optionally and independently substituted with from 1 to 5 ether, carboxylate, or sulfate moieties~~

~~said contrast agent further having:~~

~~1) an R1 observed value in a 4.5 wt% solution of HSA at 25 °C of greater than about 10 mM<sup>-1</sup> sec<sup>-1</sup>; and~~

~~2) a percent binding to HSA in a 4.5 wt%, pH 7.4 solution of HSA of greater than about 10%;~~

b) subjecting said patient to magnetic resonance imaging to determine an initial signal intensity value in a region of interest of said undesired tissue;

c) applying an interventional therapy to at least a portion of said undesired tissue in order to treat said undesired tissue, said interventional therapy selected from the group consisting of a thermal energy generation, a cryoablation, an injection of a denaturing liquid, an injection of a chemotherapeutic agent, and a photodynamic therapy; and

d) contemporaneously monitoring with magnetic resonance imaging a change in said initial signal intensity value in said region of interest of said undesired tissue during said interventional therapy; and

~~e) stopping said interventional therapy application when said change in said initial signal intensity value in said region of interest of said undesired tissue is more than about a 10% reduction in said initial signal intensity value.~~

65.-78. (Cancelled).

79. (Previously Presented) The method of claim 64, wherein said tissue is selected from the group consisting of cancerous tissue, tumorous tissue, and neoplastic tissue.

80. (Previously Presented) The method of claim 79, wherein said tissue is cancerous tissue.

81. (Previously Presented) The method of claim 64, wherein said interventional therapy application is said generation of thermal energy, and wherein said thermal energy is

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 4 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

generated by a source selected from the group consisting of one or more focused ultrasound waves, radiofrequency waves, microwaves, and lasers.

82.-84. (Cancelled).

85. (New) The method of claim 64, further comprising:

e) stopping said interventional therapy application when said change in said initial signal intensity value in said region of interest of said undesired tissue is more than about a 10% reduction in said initial signal intensity value.



Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 5 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

### REMARKS

Claims 64, 65, 67, and 71-84 were pending. The Examiner rejected claims 64, 65, 67, and 71-84. Applicants have herein amended claim 64, cancelled claims 65, 67, 71-78, and 82-84, and added claim 85. Amendments to claim 64 find support in prior claim 83 and at page 42 of the specification. New claim 85 finds support in prior claim 64. Accordingly, no new matter has been added. Thus, claims 64, 79-81, and 85 are pending.

Applicants thank the Examiner for the courtesy of the telephonic interview on September 16, 2003 to discuss the pending claims. In light of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of claims 64, 79-81, and 85.

#### Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 64, 65, 67, and 71-84 under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner stated that there was no structural relationship of elements making up the SDTBM.

Applicants respectfully disagree. The prior claims did provide a structural arrangement of the elements making up the SDTBM, as set forth more fully in the Response to Office Action filed May 21, 2003. In order to expedite prosecution, however, Applicants have herein amended claim 64 to recite the contrast agents set forth in prior claim 83. Chemical structures for the contrast agents can be found on page 42 of the specification. Accordingly, present claim 64 does provide essential structural relationships for the contrast agents to be used in the method.

Given the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

#### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner also rejected claims 64, 65, 67, and 71-84 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner stated

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 6 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

that the specification failed to describe the SDTBM as comprising "zero to six linear or branched alkyl groups having 1 to 10 carbon atoms; zero to five cycloalkyl groups, zero to five aryl groups."

Applicants respectfully disagree. As indicated more fully in the Response to Office Action filed May 21, 2003, the specification does provide written description for the SDTBM as previously claimed. In order to expedite prosecution, however, Applicants have herein amended claim 64 to recite the contrast agents set forth in prior claim 83. Support for the structure of the contrast agents can be found at page 42 of the specification. Accordingly, present claim 64 does have adequate written description in the specification.

Given the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

### CONCLUSION

In light of the amendments and remarks herein, Applicants respectfully request allowance of claims 64, 79-81, and 85. The Examiner is invited to call the under-signed attorney if such would expedite prosecution.

No fees are believed due. Please apply any other charges or credits to deposit account 06-1050.

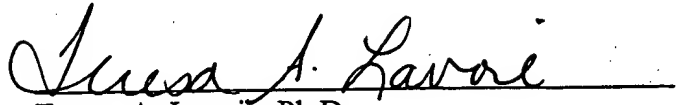
Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 7 of 7

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

Respectfully submitted,

Date: \_\_\_\_\_

9/17/03



Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

**Request  
For  
Continued Examination (RCE)  
Transmittal**

Address to:  
Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Application Number	09/887,706
Filing Date	September 8, 2000
First Named Inventor	Randall B. Lauffer et al.
Group Art Unit	1619
Examiner Name	Michael G. Hartley
Attorney Docket Number	13498-009002

**This is a Request for Continued Examination (RCE) under 37 C.F.R. §1.114 of the above-identified application.**  
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 C.F.R. §1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s)
  - a. ☐ Previously submitted. If a final Office action is outstanding, any amendment filed after the final Office action may be considered as a submission even if this box is not checked.
    - i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_
    - ii. ☐ Other \_\_\_\_\_
  - b. ☒ Enclosed
    - i. ☐ Amendment/Reply
    - ii. ☐ Affidavit(s)/Declaration(s)
    - iii. ☒ Information Disclosure Statement (IDS)
    - iv. ☒ Other copies of six references
2. **Miscellaneous**
  - a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. §1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. §1.17(i) required)
  - b. ☐ Other \_\_\_\_\_
3. **Fee** The RCE fee under 37 C.F.R. §1.17(e) is required by 37 C.F.R. §1.114 when the RCE is filed.
  - a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 06-1050
    - i. ☐ RCE fee required under 37 CFR 1.17(e)
    - ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
    - iii. ☒ Other Any deficiencies
  - b. ☒ Check in the amount of \$ 770.00 enclosed
  - c. ☐ Payment by credit card (Form PTO-2038 enclosed)

**SIGNATURE OF APPLICANT, ATTORNEY OR AGENT REQUIRED**

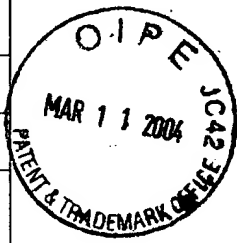
Name (Print/Type)	Teresa A. Lavoie, Ph.D.	Registration No. (Attorney/Agent)	42,782
Signature	<i>Teresa A. Lavoie</i>	Date	March 8, 2004

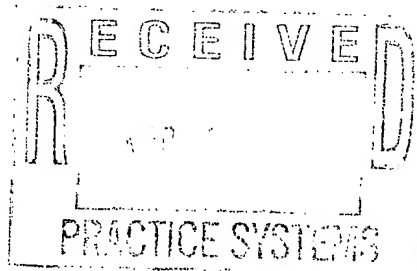
**CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type)	Angela J. Montgomery	Date	March 8, 2004
Signature	<i>Angela J. Montgomery</i>		

JAZ

Attorney's Docket No. 13498-009002	Express Mail Label No.	Mailing Date March 8, 2004	<b>For PTO Use Only</b> <i>Do Not Mark in This Area</i>  
Application No. 09/887,706	Filing Date September 8, 2000	Attorney/Secretary Init MSE/TAL/ajm	
Title of the Invention CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR MONITORING INTERVENTIONAL THERAPIES			
Applicant Randall B. Lauffer et al.			
Client Reference No. MET-7/Continuation			
Enclosures ·Check in the amount of \$770.00 ·Information Disclosure Statement (1 page) ·Form PTO-1449 (2 pages) ·Documents listed on the Form PTO-1449 (6 documents) ·Request for Continued Examination (1 page)			



am



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,706	09/08/2000	Randall B. Lauffer	MET/7 CON	3760
26191	7590	07/09/2004		

FISH & RICHARDSON P.C.  
3300 DAIN RAUSCHER PLAZA  
60 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402

EXAMINER  
HARTLEY, MICHAEL G

ART UNIT  
1616

PAPER NUMBER



DATE MAILED: 07/09/2004

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 312 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 312 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

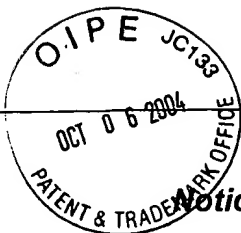
Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Docketed By Practice Systems
Action Code: <u>Issue Fee/PMA Petition</u>
Base Date: <u>7-9-04</u>
Due Date: <u>9-9-04</u>
Deadline: <u>10-9-04</u>
Initials: <u>am</u>
Record: _____

Docketed By Practice Systems
Action Code: <u>File CON-DV</u>
Base Date: <u>7-9-04</u>
Due Date: <u>9-9-04</u>
Deadline: <u>10-9-04</u>
Initials: <u>am</u>
Record: _____

Docketed By Billing Secretary
Due Date: <u>9/9/04</u>
Deadline: <u>10/9/04</u>
Initials: <u>DPS 7/14/04</u>

Docketed By Billing Secretary
Due Date: <u>9/9/04</u>
Deadline: <u>10/9/04</u>
Initials: <u>DPS 7/14/04</u>



# **Notice of Allowability**

Application No.

09/887,706

Examiner

Michael G. Hartley

Applicant(s)

LAUFFER ET AL.

Art Unit

1616

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed 3/11/2004.
2. ☒ The allowed claim(s) is/are 64,79-81 and 85.
3. ☒ The drawings filed on 06 June 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## **Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 3/11/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
Michael G. Hartley  
Primary Examiner  
Art Unit: 1616

MAR 11 2004

Sheet 1 of 2

Substitute Form PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAttorney's Docket No.  
13498-009002Application No.  
09/887,706Information Disclosure Statement  
by Applicant

(Use several sheets if necessary)

Applicant  
Randall B. Lauffer et al.Filing Date  
September 8, 2000Group Art Unit  
1619 1616

(37 CFR §1.98(b))

## U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
JP	AA	5,094,848	03/10/92	Brixner			
JP	AB	5,250,285	10/05/93	Lauffer et al.			
JP	AC	5,649,537	07/22/97	Anelli et al.			
JP	AD	5,828,215	10/27/98	Boettcher			
JP	AE	5,919,967	07/06/99	Amedeo et al.			
JP	AF	5,938,599	08/17/99	Rasche et al.			

## Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
JP	AG	WO 95/32741	12/07/95	PCT				
JP	AH	WO 96/23526	08/08/96	PCT				
JP	AI	WO 97/36619	10/09/97	PCT				
JP	AJ	WO 98/05625	02/12/98	PCT				
JP	AK	WO 00/38738	07/06/00	PCT				

## Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
JP	AL	Aime et al., "Yb(III)DOTMA as Contrast Agent in CSI and Temperature Probe in MRS," <u>Proc. Soc'y Mag. Resn.</u> , 2:1109, ISSN 1065-9889 (August 19-25, 1995)
JP	AM	Brasch et al., "Assessing Tumor Angiogenesis Using Macromolecular MR Imaging Contrast Media," <u>J. MRI</u> , 1997, 7(1):68-74
JP	AN	Carter et al., "Structure of Serum Albumin," <u>Adv. Protein Chem.</u> , 1994, 45:153-203
JP	AO	Cline et al., "MR Temperature Mapping of Focused Ultrasound Surgery," <u>Mag. Resn. Med.</u> , 1994, 31:628-636
JP	AP	Chu, "The Quantitative Analysis of Structure-Activity Relationships," <u>Burger's Medicinal Chemistry</u> , Part 1, pp. 393-418, (4 <sup>th</sup> ed. 1980)
JP	AQ	De Poorter et al., "Noninvasive MRI Thermometry with the Proton Resonance Frequency (PRF) Method: <i>In Vivo</i> Results in Human Muscle," <u>Mag. Resn. Med.</u> , 1995, 33:74-81
JP	AR	Dodd et al., "MRI monitoring of the effects of photodynamic therapy on prostate tumours," <u>Proc. Soc'y Mag. Resn.</u> , 3:1368, ISSN 1065-9889 (August 19-25, 1995)
JP	AS	Dupas et al., "Delineation of Liver Necrosis Using Double Contrast-Enhanced MRI," <u>J. MRI</u> , 1997, 7(3):472-477
JP	AT	He et al., "Atomic Structure and Chemistry of Human Serum Albumin," <u>Nature</u> , 1992, 358:209-215

Examiner Signature

MARTLEY

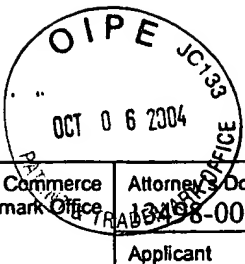
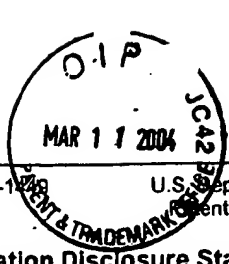
Date Considered

7/1/2004

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form (PTO-1449)





Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 13498-009002	Application No. 09/887,706
<b>Information Disclosure Statement</b> by Applicant (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Randall B. Lauffer et al.	
		Filing Date September 8, 2000	Group Art Unit 1619 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
o	AU	Honda et al., "Percutaneous Hot Saline Injection Therapy for Hepatic Tumors: An Alternative to Percutaneous Ethanol Injection Therapy," <u>Radiology</u> , 1994, 190:53-57
o	AV	Horrocks et al., "Lanthanide Ion Luminescence in Coordination Chemistry and Biochemistry," <u>Progr. Inorg. Chem.</u> , 1984, 31:1-104
o	AW	Hynynen et al., "The Usefulness of a Contrast Agent and Gradient-Recalled Acquisition in a Steady-State Imaging Sequence for Magnetic Resonance Imaging-Guided Noninvasive Ultrasound Surgery," <u>Invest. Radiol.</u> , 1994, 29:897-903
o	AX	Hynynen et al., "The feasibility of using MRI to monitor and guide noninvasive ultrasound surgery," <u>Ultrasound in Med. And Biol.</u> , 1993, 19(1):91-92
o	AY	Kragh-Hansen, "Molecular Aspects of Ligand Binding to Serum Albumin," <u>Pharm. Rev.</u> , 1981, 33:17-53
o	AZ	Lauffer, "Paramagnetic Metal Complexes as Water Proton Relaxation Agents for NMR Imaging: Theory and Design," <u>Chem. Rev.</u> , 1987, 87:901-927
o	AAA	Lauffer et al., "MS-325: A Small-Molecule Vascular Imaging Agent for Magnetic Resonance Imaging," <u>Acad. Radiol.</u> , 1996, Supplement 02, 3:S356-358
o	ABB	Leo et al., "Partition Coefficients and Their Uses," <u>Chem. Rev.</u> , 1971, 71:525-616
o	ACC	Nagel et al., "Contrast-enhanced MR Imaging of Hepatic Lesions Treated with Percutaneous Ethanol Ablation Therapy," <u>Radiology</u> , 1993, 189:265-270
o	ADD	Päuser et al., "Evaluation of Efficient Chemoembolization Mixtures by Magnetic Resonance Imaging Therapy Monitoring: An Experimental Study on the VX2 Tumor in the Rabbit Liver," <u>Cancer Res.</u> , 1996, 56:1863-1867
o	AEE	Rossi et al., "Percutaneous RF Interstitial Thermal Ablation in the Treatment of Hepatic Cancer," <u>AJR</u> , 1996, 167:759-768
o	AFF	Saint-Jalmes, "Precision in Temperature Measurement via T <sub>1</sub> or Diffusion Imaging," <u>Proc. Soc'y Mag. Resn.</u> , 2:1072, ISSN 1065-9889 (August 19-25, 1995)
o	AGG	Schwarzmaier et al., "Magnetic Resonance Imaging of Microwave Induced Tissue Heating," <u>Mag. Resn. Med.</u> , 1995, 33:729-731
o	AHH	Seibel, "Image-guided minimally invasive therapy," <u>Surg. Endosc.</u> , 1997, 11:154-162
o	AII	Tracz et al., "Comparison of Magnetic Resonance Images and the Histopathological Findings of Lesions Induced by Interstitial Laser Photocoagulation in the Brain," <u>Lasers in Surgery and Medicine</u> , 1993, 13:45-54
o	AJJ	Villringer et al., "Dynamic Imaging with Lanthanide Chelates in Normal Brain: Contrast Due to Magnetic Susceptibility Effects," <u>Mag. Resn. Med.</u> , 1988, 6:164-174
o	AKK	Vogl et al., "Recurrent Nasopharyngeal Tumors: Preliminary Clinical Results with Interventional MR Imaging-controlled Laser-induced Thermotherapy," <u>Radiology</u> , 1995, 196:725-733
o	ALL	Webb et al., "Measurement of microwave induced heating of breast tumors in animal models using cobalt based NMR," <u>Proc. Soc'y Mag. Resn.</u> , 1:72, ISSN 1065-9889 (August 19-25, 1995)
o	AMM	Webb et al., "Microencapsulation of fluorine-containing phase transition agents for monitoring temperature changes in-vivo," <u>Proc. Soc'y Mag. Resn.</u> , 3:1574, ISSN 1065-9889 (August 6-12, 1994)

Examiner Signature - J. MARTLEY	Date Considered 7/1/2004
EXAMINER: Initials citation considered/ Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

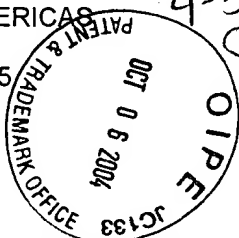
HSE  
TAL

## UNITED STATES PATENT AND TRADEMARK OFFICE

13498-009002

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/887,706	09/08/2000	Randall B. Lauffer	MET/7 CON

1473  
FISH & NEAVE  
1251 AVENUE OF THE AMERICAS  
50TH FLOOR  
NEW YORK, NY 10020-1105

CONFIRMATION NO. 3760

## FORMALITIES LETTER



\*OC000000007748497\*

Date Mailed: 03/29/2002

## NOTICE OF INCOMPLETE NONPROVISIONAL APPLICATION

## FILED UNDER 37 CFR 1.53(b)

A filing date has NOT been accorded to the above-identified application papers for the reason(s) indicated below.

All of the items noted below and a newly executed oath or declaration covering the items must be submitted within **TWO MONTHS** of the date of this Notice, unless otherwise indicated, or proceedings on the application will be terminated (37 CFR 1.53(e)).

The filing date will be the date of receipt of all items required below, unless otherwise indicated. Any assertions that the item(s) required below were submitted, or are not necessary for a filing date, must be by way of petition directed to the attention of the Office of Petitions accompanied by the \$130.00 petition fee (37 CFR 1.17(h)). If the petition states that the application is entitled to a filing date, a request for a refund of the petition fee may be included in the petition.

- The application was deposited without drawings. 35 U.S.C. 113 (first sentence) requires a drawing "where necessary for the understanding of the subject matter sought to be patented." Applicant should reconsider whether the drawings are necessary under 35 U.S.C. 113 (first sentence).

A copy of this notice MUST be returned with the reply.

Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

\*Also Docketed  
Already Docketed by Practice Systems

Action Code: 2 MD. Petition APR 02 2002

Due Date: 5-4-02

Deadline: 5-4-02

Initials: [Signature]

FISH &amp; NEAVE - PATENT DEPT

REFERRED TO

NOTED BY

CLA 4-17-02

DOCKETED BY PRACTICE SYSTEMS

ACTION: Incomplete Appn.

BASE: 3-29-02

DUE: 5-29-02

DEADLINE: 5-29-02

INITIALS: [Signature]

Docketed By Billing Secretary

Due Date: 5/29/02

Deadline: 5/29/02

Initials: DAS 4/16/02

CC 4-17-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Randall B. Lauffer et al.                      Art Unit : Not yet assigned  
Serial No. : 09/887,706                                      Examiner : Not yet assigned  
Filed : September 8, 2000  
Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

Office of Petitions  
Commissioner of Patents  
Washington D.C. 20231

PETITION UNDER 37 C.F.R. §§1.17(h), 1.53(e), and 1.181 TO ACCORD A FILING DATE

Pursuant to 37 CFR §§1.17(h), 1.53(e) and in response to the Notice of Incomplete Provisional Application mailed 3/29/2002, Applicants hereby timely petition to accord the above-referenced application a filing date of 9/8/2000 under §1.53(e). The application was not granted a filing date for failure to deposit drawings. Applicants, however, submit that the drawings "are not necessary for the understanding of the subject matter as sought to be patented" under 35 U.S.C. §113, and therefore that the application is entitled to its filing date of 9/08/2000.

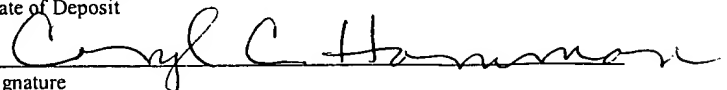
Applicants assert that the drawings are not necessary for an understanding of the subject matter for the following reasons. The application makes reference to 3 drawings, entitled Figures 1-3. Applicants point out that these drawings are merely graphical representations of the data presented in tabular form in Tables 1-3. Tables 1-3 were included in the specification as filed. Therefore, the graphical representation of the data in Figures 1-3 is duplicative of the information provided in Tables 1-3.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

May 28, 2002

Date of Deposit

  
Signature

Caryl C. Harriman

Typed or Printed Name of Person Signing Certificate

Attached to this petition are true copies of omitted Figures 1-3,<sup>1</sup> the Brief Description of Figures 1-3 from the specification, and the specification pages which incorporate Tables 1-3 ("Experimental" section). Applicants first point to the Brief Description of Figures 1-3, which notes for each figure that it is a "graphical representation." Secondly, Applicants point to the specification pages incorporating Tables 1-3 ("Experimental" section). For Examples 1-3, Applicants refer to each table and figure as representing the same information. For example, on page 58, Applicants note "[s]ee Table 1 below and Figure 1." In addition, Applicants note on page 59 "[a]s Table 1 and Figure 1 show . . . ." The corresponding language similarly appears on pages 60 and 61 for Table 2 and Figure 2, and on pages 62 and 63 for Table 3 and Figure 3. Finally, a visual comparison of the Figures with the Tables indicates the correspondence between the two sets of data.

Based on the foregoing evidence, Applicants assert that the drawings are not necessary for an understanding of the subject matter under 35 U.S.C. §113 (first sentence). Accordingly, Applicants respectfully request that the application be accorded a filing date of 9/8/2000. Applicants note that a preliminary amendment of the specification to cancel all references to omitted drawings is presently being prepared.

Please charge Deposit Account No. 06-1050 to cover the \$130 fee for this petition. Because Applicants assert however that the application is entitled its filing date, this fee should be refunded. Please apply any other charges or credits to Deposit Account No. 06-1050. Copies of the Notice of Incomplete Nonprovisional Application and of this petition are enclosed.

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<sup>1</sup> Figures 1-3 attached are copies of Figures 1-3 included in the parent application 08/942,989 as well as copies of the same taken from the corresponding PCT application WO 99/17809, which claims priority from the parent application.

Applicant : Randall B. Lauffer et al.  
Serial No. : 09/887,706  
Filed : September 8, 2000  
Page : 3

Attorney's Docket No.: 13498-009002 / MET-  
7/Continuation

Respectfully submitted,

Date: 5/28/02

Teresa A. Lavoie  
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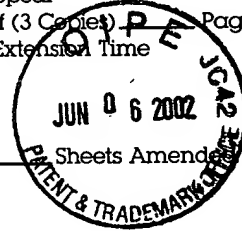
PATENT

ATTORNEY DOCKET NO.: 13498-091002

The Patent and Trademark Office date stamp sets forth the date of receipt of:

Applicant or Patentee Lauffer et al.  
No. (Application, Appeal, Interference, Patent, Reexam) 09/887,706  
Filing or Issue Date September 8, 2002  
Title: Contrast-Enhanced Diagnostic Imaging

- ☒ Transmittal Letter (1 Copies) ☐ With Pet. for Ext.
- |   |  |
|---|--|
| <input type="checkbox"/> Assignment   | <input type="checkbox"/> Status Inquiry                      |
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| <input type="checkbox"/> Maintenance Fee  | <input type="checkbox"/> Request Certificate of Correction   |
| <input type="checkbox"/> Check \$ _____   | <input type="checkbox"/> Notice of Appeal                    |
| <input type="checkbox"/> Deposit Account Order Form (2 Copies)                    | <input type="checkbox"/> Appeal Brief (3 Copies) _____ Pages |
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| <input type="checkbox"/> Prior Art References-Number of References _____          |  |
| <input type="checkbox"/> Drawings _____ Sheets Formal _____ Sheets Informal _____ | <input type="checkbox"/> Sheets Amended _____                |
| <input type="checkbox"/> Notice of Missing Parts                                  |  |
| <input type="checkbox"/> Combined Declaration and Power of Attorney               |  |
| <input type="checkbox"/> Small Entity Statement                                   |  |



☒ Other Petition (3 pgs.) (2 copies): Copy of Notice of Incomplete Provisional (pg. 1); Figs. from App. (3 sheets); Figs. from RPT (3 sheets); Brief doc. (2 pgs.)  
Atty/Sec \_\_\_\_\_ Client/ \_\_\_\_\_  
Initials TAU Matter Name EP1X Experimental Section (pgs. 57-64) Date 5-28-02

CCH

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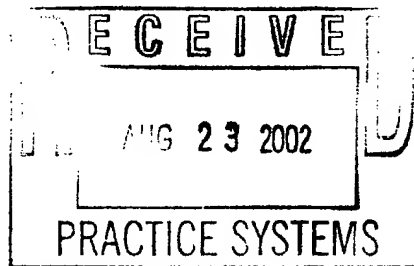


UNITED STATES PATENT AND TRADEMARK OFFICE

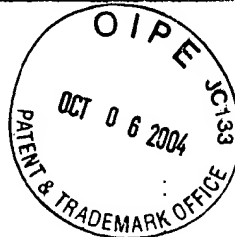
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WASHINGTON, D.C. 20231  
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JGJr: 07-02

Paper No. 7



MARK S. ELLINGER  
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MINNEAPOLIS, MN 55402



COPY MAILED

AUG 19 2002

OFFICE OF PETITIONS

DECISION ON PETITION

In re Application of  
Lauffer, et al.  
Application No. 09/887,706  
Filed: 8 September, 2000  
Attorney Docket No.:  
13498-009002/MET-7/Continuation

This is a decision on the petition filed on 6 June, 2002, under 37 C.F.R. §1.53(e)<sup>1</sup> and §1.181<sup>2</sup>  
"To Accord a Filing Date"--notably, however, Petitioners contend that the drawings found to be

<sup>1</sup> The regulations at 37 C.F.R. §1.53 provide in pertinent part:  
§ 1.53 Application number, filing date, and completion of application. \*\*\*

(e) Failure to meet filing date requirements.

(1) If an application deposited under paragraph (b), (c), or (d) of this section does not meet the requirements of such paragraph to be entitled to a filing date, applicant will be so notified, if a correspondence address has been provided, and given a time period within which to correct the filing error.

(2) Any request for review of a notification pursuant to paragraph (e)(1) of this section, or a notification that the original application papers lack a portion of the specification or drawing(s), must be by way of a petition pursuant to this paragraph accompanied by the fee set forth in § 1.17(h). In the absence of a timely (§ 1.181(f)) petition pursuant to this paragraph, the filing date of an application in which the applicant was notified of a filing error pursuant to paragraph (e)(1) of this section will be the date the filing error is corrected.

(3) If an applicant is notified of a filing error pursuant to paragraph (e)(1) of this section, but fails to correct the filing error within the given time period or otherwise timely (§ 1.181(f)) take action pursuant to this paragraph, proceedings in the application will be considered terminated. Where proceedings in an application are terminated pursuant to this paragraph, the application may be disposed of, and any filing fees, less the handling fee set forth in § 1.21(n), will be refunded.

\*\*\*

<sup>2</sup> The regulations at 37 C.F.R. §1.181 provide, in pertinent part:  
§1.181 Petition to the Commissioner.

(a) Petition may be taken to the Commissioner: (1) From any action or requirement of any examiner in the *ex parte* prosecution of an application which is not subject to appeal to the Board of Patent Appeals and Interferences or to the court; (2) In cases in which a statute or the rules specify that the matter is to be determined directly by or reviewed by the Commissioner; and (3) To invoke the supervisory authority of the Commissioner in appropriate circumstances. \*\*\*

(b) Any such petition must contain a statement of the facts involved and the point or points to be reviewed and the action requested. Brief or memoranda, if any, in support thereof should accompany or be embodied in the petition; and where facts are to be proven, the proof in the form of affidavits or declaration (and exhibits, if any) must accompany the petition.

(c) When a petition is taken from an action or requirement of an examiner in the *ex parte* prosecution of an application, it may be required that there have been a proper request for reconsideration (§1.111) and a repeated action by the examiner. The examiner may be directed by the Commissioner to furnish a written statement, within a specified time, setting forth the reasons for his decision upon the matters averred in the petition, supplying a copy thereof to the petitioner.

(d) Where a fee is required for a petition to the Commissioner the appropriate section of this part will so indicate. If any required fee does not accompany the petition, the petition will be dismissed. \*\*\*

(f) Except as otherwise provided in these rules, any such petition not filed within 2 months from the action complained of, may be dismissed as untimely. The mere filing of a petition will not stay the period for reply to an Examiner's action which may be running against an application, nor act as a stay of other proceedings.

\*\*\*

RME

QAS 8/26/02

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missing from the application “are not necessary for the understanding of the subject matter as sought to be patented.”

For the reasons set forth below, the petition is **GRANTED in part**.<sup>3</sup>

The application was filed on 8 September, 2001.

Following a 4 March, 2002, Decision under 37 C.F.R. §1.10, on 29 March, 2002, the Office mailed a “Notice of Incomplete Nonprovisional Application” indicating that the application was filed without drawings as required under 35 U.S.C. §113 (first sentence). Petitioners respond with the instant petition stating that:

- the drawings found to be missing from the application “are not necessary for the understanding of the subject matter as sought to be patented”; and
- with regard to the absent Figures 1 - 3, Petitioners refer each figure to a comparable table in the specification, with the table and the figure as representing the same information set forth in the specification by the tables at page 58 (for Figure 1), pages 60 and 61 (for Figure 2) and pages 62 and 63 (for Figure 3).

Thus, Petitioners contend, the drawings are not necessary for the understanding of the subject matter as sought to be patented.

It is the practice of the Office to treat an application that contains at least one process or method claim as an application for which a drawing is not necessary for the understanding of the invention under 35 U.S.C. §113 (first sentence). (See: MPEP §601.01<sup>4</sup>)

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<sup>3</sup> Pursuant to Petitioner's authorization, the petition fee (\$130.00) is refunded to Deposit Account 06-1050.

<sup>4</sup> The commentary at MPEP §601.01 provides in pertinent part:

\* \* \*

**601.01(f) Applications Filed Without Drawings**

35 U.S.C. 111(a)(2)(B) and 35 U.S.C. 111(b)(1)(B) each provide, in part, that an “application shall include . . . a drawing as prescribed by section 113 of this title” and 35 U.S.C. 111(a)(4) and 35 U.S.C. 111(b)(4) each provide, in part, that the “filing date . . . shall be the date on which . . . any required drawing are received in the Patent and Trademark Office.” 35 U.S.C. 113 (first sentence) in turn provides that an “applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented.

Applications filed without drawings are initially inspected to determine whether a drawing is referred to in the specification, and if not, whether a drawing is necessary for the understanding of the invention. 35 U.S.C. 113 (first sentence).

It has been USPTO practice to treat an application that contains at least one process or method claim as an application for which a drawing is not necessary for an understanding of the invention under 35 U.S.C. 113 (first sentence). The same practice has been followed in composition applications.

\* \* \*

A nonprovisional application having at least one claim, or a provisional application having at least some disclosure, directed to the subject matter discussed above for which a drawing is usually not considered essential for a filing date, not describing drawing figures in the specification, and filed without drawings will simply be processed for examination, so long as the application contains something that can be construed as a written description. A nonprovisional application having at least one claim, or a provisional application having at least some disclosure, directed to the subject matter discussed above for which a drawing is usually not considered essential for a filing date, describing drawing figure(s) in the specification, but filed without drawings will be treated as an application filed without all of the drawing figures referred to in the specification as discussed in MPEP § 601.01(g), so long as the application contains something that can be construed as a written description. In a situation in which the appropriate Technology Center (TC) determines that drawings are necessary under 35 U.S.C. 113 (first sentence) the filing date issue will be reconsidered by the





THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Randall B. Lauffer et al.      Art Unit : 1616  
Serial No. : 09/887,706      Examiner : Michael G. Hartley  
Filed : September 8, 2000  
Title : CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR  
MONITORING INTERVENTIONAL THERAPIES

**Mail Stop Issue Fee**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL

The following correspondence relating to this application is enclosed for filing:

1. Response to Notice of Allowance;
2. Part B - Issue Fee Transmittal;
3. Check in the amount of \$1,670.00;
4. Application for Patent Term Adjustment with 8 attachments;
5. Check in the amount of \$200.00; and
6. A Return Postcard.

Please date stamp and return the enclosed postcard.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 10/6/04

Teresa A. Lavoie  
Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

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60 South Sixth Street  
Suite 3300  
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(612) 335-5070 telephone  
(612) 288-9696 facsimile

60250138.doc

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV467324605US

October 6, 2004  
Date of Deposit

# PART B – FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

26191

7590

07/09/2004

FISH & RICHARDSON P.C., P.A.  
60 SOUTH SIXTH STREET  
SUITE 3300  
MINNEAPOLIS, MN 55402



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for express mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

EV467324605US

(Express Mail No.)

10/06/2004

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,706	09/08/2000	Randall B. Lauffer	13498-009002	3760

TITLE OF INVENTION: CONTRAST-ENHANCED DIAGNOSTIC IMAGING METHOD FOR MONITORING INTERVENTIONAL THERAPIES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1370	\$0	\$1370	10/09/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
HARTLEY, MICHAEL G.	1616	424-117000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. Fish & Richardson P.C., P.A.

2.

3.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE (CITY and STATE OR COUNTRY)

Epix Medical, Inc.

Cambridge, MA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☒ Issue Fee

☐ Publication Fee

☒ Advance Order - # of Copies 10

4b. Payment of Fee(s):

☒ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number 06-1050 (enclose an extra copy of this form).

Director of Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

*Teresa A. Lavoie*

Teresa A. Lavoie, Ph.D. (Date) October 6, 2004  
42,782

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

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